REMARKS

Applicants request acceptance of the claims of the present application in view of the above amendments and the following remarks.

OBJECTIONS

As requested by the Examiner, the following statement has been incorporated at the beginning of the specification: "This application is a continuation of application Serial No. 10/008,516, filed November 8, 2001, now US Patent No. 6,649,607."

As requested by the Examiner, Applicants have amended claims 30-32 to overcome the Examiner's objections.

REJECTIONS

Claims 28 and 29 have been rejected under 35 U.S.C. 102(a) as being anticipated by the Landry et al reference. The Landry reference teaches the use of (R)-tofisopam for the prevention and treatment of anxiety and anxiety disorders. (R)-tofisopam was found to be the active isomer of racemic

tofisopam in the head twitch assay described in column 21, lines 24-34. (S)-tofisopam was used in the assay merely to show that the (S)-enantiomer was inactive in the assay. Thus, the Landry reference does not anticipate, teach or suggest the present invention which describes (S)-tofisopam as an active pharmaceutical ingredient which can be used to effectively treat a disease.

Claims 1-5 have been cancelled. Claim 28 has been amended to delete the oral administration method while retaining the intraperitoneal, subcutaneous, intranasal, intramuscular, intrathecal, sublingual, rectal, intravenous and transdermal delivery options. The Landry reference does not anticipate these delivery methods. Nor does the Landry reference teach or suggest that S-tofisopam could be administered by these methods.

Furthermore, the amendment to claim 29 deletes the language "approximately". As the Examiner pointed out in the communication dated August 16, 2004, the Landry reference describes the administration of S-tofisopam at 30 mg/kg in rats. This would correspond to a dosage of 7.5 mg to 9 mg of S-tofisopam. Amending claim 29 to delete "approximately"

establishes that the doses considered are above the dose range disclosed. The Landry reference does not anticipate claim 29. Nor does the Landry reference teach or suggest the use of doses of 10 mgs or greater of tofisopam, because the use of S-tofisopam at 7.5 mg to 9 mg was not effective.

Applicants have added additional claims dependent on claim 29 to cover the different dose ranges.

None of these amendments introduces new matter.

Applicants kindly request that the claims be accepted in view of the remarks and amendments provided above.

Respectfully submitted,

Karen Guerrero
Reg. No. 37,071
Attorney for Applicants
3528 Old Baptist Rd
Collegeville, PA 19426
Tel.: (609) 771-8660 ext. 118

05/03/2005 11:07 AM

CLAIMS WITH MARKUPS

1-27 (Cancelled

28. (Currently amended) A [The] pharmaceutical composition comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier, [according to claim 1,] wherein the composition is for intraperitoneal, subcutaneous, intranasal, intramuscular, intrathecal, sublingual, rectal, intravenous infusion, or transdermal delivery [or oral administration].

29. (Currently amended) A [The] pharmaceutical composition comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier [according to claim 1], wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from ~~approximately~~ 10 mg to 1200 mg.

30. (Currently amended) The pharmaceutical composition of claim 29, comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier [according to claim 1], wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 50 mg to 600 mg.

31. (Currently amended) The pharmaceutical composition of claim 29, comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier [according to claim 1], wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 100 mg to 400 mg.

32. (Currently amended) A method of administering a pharmaceutical comprising a therapeutically effective amount of S-tofisopam, a prodrug or pharmaceutically acceptable salt thereof, substantially free of its R-enantiomer, with a pharmaceutically acceptable carrier,

comprising preparing the pharmaceutical composition comprising S-tofisopam, pro-drug or pharmaceutically acceptable salt thereof and a pharmaceutically effective carrier and administering the pharmaceutical composition at a dose of less than 30 mg/kg.

33. (New) The pharmaceutical composition according to claim 28, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 10 mg to 1200 mg.

34. (New) The pharmaceutical composition according to claim 28, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 50 mg to 600 mg.

35. (New) The pharmaceutical composition according to claim 28, wherein the amount of S-tofisopam, prodrug, or a pharmaceutically acceptable salt thereof is from 100 mg to 400 mg.